Complete Summary

GUIDELINE TITLE

ACR practice guideline for the performance of high-dose-rate brachytherapy.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). ACR practice guideline for the performance of high-dose-rate brachytherapy. Reston (VA): American College of Radiology (ACR); 2005. 5 p. [19 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Radiology (ACR). ACR practice guideline for the performance of high-dose-rate brachytherapy. Reston (VA): American College of Radiology (ACR); 2000.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cancer

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Radiation Oncology
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To assist practitioners in providing appropriate radiologic care for patients
- To describe principles of practice for high-dose-rate (HDR) brachytherapy in radiation oncology

TARGET POPULATION

Patients undergoing high-dose-rate (HDR) brachytherapy

Note: This guideline does not apply to patients undergoing intravascular brachytherapy.

INTERVENTIONS AND PRACTICES CONSIDERED

1. High-dose-rate (HDR) brachytherapy including
    - Clinical evaluation
    - Establishing treatment goals
    - Obtaining informed consent
    - Applicator insertion
    - Treatment planning, delivery, and summary
    - Follow-up at regular intervals
2. Qualifications of personnel
3. Periodic equipment maintenance
4. Patient and personnel safety measures
5. Continuing medical education for medical staff

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each practice guideline and technical standard, representing a policy statement by the American College of Radiology (ACR), has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines are approved by the Commission on Quality and Safety as well as the American College of Radiology (ACR) Board of Chancellors, the ACR Council Steering Committee, and the ACR Council.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Brachytherapy is the use of radioactive isotopes to treat malignancies or benign conditions by means of a radioactive source placed close to or into the tumor or treatment site. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer. Such treatment can be given as interstitial, intracavitary, or intraluminal therapy. High-dose-rate (HDR) brachytherapy uses highly active isotopes, including iridium-192 and cobalt-60, at dose rates of 20 or more cGy per minute at a designated point. HDR brachytherapy is indicated for treatment of malignancies where the treatment site can be well defined and is accessible to applicators to hold the sources. This guideline does not apply to intravascular brachytherapy.

The use of brachytherapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education.

Process of Brachytherapy

The use of HDR brachytherapy is a complex process involving trained personnel who must work in concert to carry out a variety of interrelated activities. Communication among brachytherapy team members and well-defined procedures are essential for accurate and safe treatment.

A. Clinical Evaluation

The initial evaluation of the patient includes history, physical examination, review of pertinent diagnostic studies and reports, and communication with the referring physician and other physicians involved in the patient's care. The extent of the tumor must be determined and recorded for staging; this will facilitate treatment decisions, determine the prognosis of the patient, and enable a comparison of treatment results.

B. Establishing Treatment Goals

The goal of treatment (curative, palliative, or to establish local tumor control) should be documented as clearly as possible. Treatment options and their relative merits and risks should be discussed with the patient. Integration of brachytherapy with external beam therapy should be defined. A summary of the evaluation should be communicated to the referring physician.

C. Informed Consent

Informed consent must be obtained and documented.

D. Applicator Insertion

Oncologic practice, including brachytherapy, commonly requires the interaction of multiple specialists. The choice and placement of after-loading applicators and loading and unloading of radioactive sources are the responsibility of the radiation oncologist.

Each type of brachytherapy procedure has its own set of unique characteristics. The brachytherapy team should operate according to an established system of procedural steps that have been developed by the radiation oncologist and brachytherapy team members. This systematic approach to applicator or source insertion should include a description of preimplantation steps, sedation or anesthesia procedures, the specific applicators used, and the insertion techniques. Standard orders or care guidelines may enhance the systematic approach to the insertion process.

E. Treatment Planning

HDR brachytherapy is administered according to the written, signed, and dated prescription of the radiation oncologist. Before treatment, the final prescription must designate the treatment site, the isotope, the number of source positions, the planned dose, the dose per fraction, the number of fractions, and the time interval between HDR fractions. Applicator geometry and isotope dwell positions are defined with localization images or computed tomography (CT) scans, as is the location of the normal dose-limiting structures, as delineated by urinary bladder catheter bulb, rectal marker/contrast, or retractor or vaginal packing. Computerized dosimetry is performed by the medical physicist or his/her designee and approved by the radiation oncologist before the treatment proceeds. Independent verification of brachytherapy parameters (by another person or another method) is done pretreatment (see Patient and Personnel Safety section, below). Optimization techniques to shape the dose distribution are widely available but should be used carefully to avoid undetected hot and cold spots.

F. Treatment Delivery

Prior to each delivery session, the medical physicist or radiation oncologist should verify the proper connection of each applicator to the planned delivery channel. The medical physicist should verify all treatment parameters at the HDR console prior to treatment, including the correspondence between planned source strength and after-loader source strength with appropriate corrections for decay and source changes.

HDR treatment is delivered by remote after-loading of high-activity sources. Radiation safety considerations are essential for HDR procedures. The radiation oncologist and the medical physicist must be in the immediate vicinity at all times while HDR brachytherapy is being administered, and the patient and functioning of equipment must be continuously monitored by video or audio means and/or direct observation. Treatment delivery must be subject to detailed scrutiny as described in the Patient and Personnel Safety

section (see below). At the end of each treatment, the patient and the room must be surveyed to ensure that the source has been retracted into the after-loading device.

G. Treatment Summary

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters should be generated, including the total dose of brachytherapy and the total dose of external beam therapy if given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition.

H. Follow-up Evaluation

Patients treated with HDR brachytherapy should be evaluated at regular intervals by the radiation oncologist for response and early and late effects on normal tissues.

Qualifications of Personnel

The HDR brachytherapy team includes the physician(s), medical physicist, dosimetrist, radiation therapist, nurse, and radiation safety officer. HDR brachytherapy requires extensive interaction between all members of the team. Because treatment is given with such a highly active source over a short duration, the consequences of error and possible misadministration are potentially increased with HDR brachytherapy. Communication among team members and well-defined procedures for performing HDR brachytherapy are essential for accurate and safe treatment. Qualifications of the brachytherapy team include the credentials listed below:

A. Radiation Oncologist

Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program in radiation oncology.

or

Certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology. Alternatively, certification in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec, may be considered proof of adequate physician qualifications.

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields in medical physics, and to

be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR).

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

C. Radiation Therapist

Must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy.

D. Medical Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

E. Nurse

State licensure as a registered nurse or practical nurse is recommended.

Equipment

HDR brachytherapy treatment is delivered with computerized, remotely after-loaded devices that contain a specific radioactive source. Equipment manufacturers offer applicators for interstitial, intracavitary, and intraluminal treatment that are used with the treatment units. An applicator replacement schedule should be implemented to avoid damage caused by excessive use. Computerized treatment planning is accomplished with specialized hardware and software compatible with the respective HDR brachytherapy system being used.

Periodic scheduled preventive maintenance is essential. The medical physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of manual equipment, remote after-loading units, and applicators. (See the ACR Technical Standard for the Performance of Brachytherapy Physics: Remotely Loaded HDR Sources.)

Patient and Personnel Safety

Patient protection measures include those related to medical safety and radiation protection.

A. Patient protection measures should include:
    1. A radiation exposure-monitoring program, as required by the Nuclear Regulatory Commission (NRC) or appropriate state agencies.
    2. Annual training of staff in emergency procedures in case of equipment malfunction.

3. Charting systems for prescription, definition and delivery of treatment parameters, and recording and summation of HDR brachytherapy and external beam therapy treatment.
4. A physics program for ensuring accurate dose delivery to the patient.
5. A system for the radiation oncologist and medical physicist to verify independently (by another person or another method) all brachytherapy parameters to be used in each procedure (source, isotope and activity, dose rate, total dose, treatment duration, etc.) prior to institution of HDR brachytherapy.

B. Personnel safety measures should include:
    1. A radiation exposure-monitoring program, as required by the Nuclear Regulatory Commission or appropriate state agencies.
    2. Routine leak testing of all sealed sources, as required by regulatory agencies.
    3. Appropriate safety equipment for use of sealed sources.

Educational Program

Continuing medical education programs should include radiation oncologists, medical physicists, dosimetrists, nurses, and radiation therapy staff. Radiation safety programs should also include hospital-based personnel who will be involved with brachytherapy patients. Educational programs initially and for retraining must cover the following:

A. The safe operation, including emergency procedures, of HDR applicators and HDR remote after-loading equipment and sources as appropriate to the individual's responsibilities.
B. Treatment techniques and new developments in radiation oncology and brachytherapy.

The program should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

Documentation

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns

See the "Description of the Implementation Strategy" field, below.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate performance of high-dose-rate brachytherapy to ensure accurate and safe treatment

POTENTIAL HARMS

- Side effects of brachytherapy
- Because treatment is given with highly active source over a short duration, the consequences of error and possible misadministration are potentially increased with high-dose-rate (HDR) brachytherapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth in the guideline, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.
- The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care.
- To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.
- The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to

these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

Note: The licensing of radioactive sources and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states.* Medical use of isotopes for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies. Detailed descriptions of NRC licensing and safety issues can be found in the Code of Federal Regulations, Part 20 and Part 35. State requirements for the agreement states are found in the respective state statutes.

*An agreement state is any state with which the United States (US) Nuclear Regulatory Commission or the US Atomic Energy Commission has entered into an effective agreement under Subsection 274.b of the Atomic Energy Act of 964, as amended (73 Stat. 689).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the National Guideline Clearinghouse (NGC) summary of the American College of Radiology (ACR) Practice Guideline for Radiation Oncology. It is the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The director will designate appropriate personnel to constitute the CQI Committee that will review high-dose-rate (HDR) brachytherapy as part of the CQI meeting agenda. Refer to the NGC summary of the ACR Practice Guideline for Radiation Oncology for a detailed description of CQI Committee functions.

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). ACR practice guideline for the performance of high-dose-rate brachytherapy. Reston (VA): American College of Radiology (ACR); 2005. 5 p. [19 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology

GUIDELINE COMMITTEE

Guidelines and Standards Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Laurie E. Gaspar, MD, MBA, *Chair*; E. Brian Butler, MD; Nancy A. Ellerbroek, MD; Beth A. Erickson, MD; Cassandra S. Foens, MD; Song K. Kang, MD; Peter M. Mauch, MD; Tariq A. Mian, PhD; Seth A. Rosenthal, MD; Anthony H. Russell, MD; Oscar E. Streeter, Jr., MD; Vipul V. Thakkar, MD; Frank A. Vicini, MD; Steven A. Leibel, MD, Chair, Commission

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Radiology (ACR). ACR practice guideline for the performance of high-dose-rate brachytherapy. Reston (VA): American College of Radiology (ACR); 2000.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR practice guidelines and technical standards purpose and intended use. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- The process for developing ACR practice guidelines and technical standards. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 17, 2007. The information was verified by the guideline developer on May 29, 2007.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/15/2008